

ACKNOWLEDGEMENT OF INTERVIEW

An interview, granted by the Examiner and held on December 4, 2008, is gratefully acknowledged. During the interview, claim 1 was discussed with respect to the applicability of prior art references, as related to the showings or EMS in combination with the use of Botulinum toxin . In the interview, the issue of showing of synergy was discussed, and Applicant's representative indicated that an amended claim which would specify the synergistic functions.

The interview is believed to have expedited the prosecution of this case, and the Examiner's extra efforts in this regard are appreciated.

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated September 19, 2008, are respectfully requested in view of this amendment. By this amendment, Claims 1 and 7 have been amended and new claims 19 and 20 are submitted. Claims 1-20 are pending in this application.

Claims 1 and 7 have been amended to set forth the administering of the Botulinum toxin, synergistically interacting with the electromagnetic signals, by inducing a non-specific immune response to further enhance the bone density stimulation of the exposure of the patient to the electromagnetic signals. Support is found in the specification, *inter alia* at page 15, lines 19 to 25 of the PCT application.

New claims 19 and 20 set forth the effect of the combination, specifically in increase in BMMD and subsequent decrease in fracture risk. Support is found at page 15, lines 21-23. It is respectfully submitted that the above amendments introduce no new matter within the meaning of 35 U.S.C. §132.

Rejections Under 35 U.S.C. §103

In the Office Action, Claims 1, 2, 6-8, and 12-18 were again rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,443,883 issued to

Ostrow et al. ("Ostrow") in view of U.S. Patent No. 6,464,986 issued to Aoki et al. ("Aoki"). Claims 1, 3, 6, 7, 9, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent Application Publication No. 2004/0077921 applied for by Becker et al. ("Becker") in view of *Aoki*. Claims 1-5, 7-11, and 13-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 4,674,482 issued to Waltonen et al. ("Waltonen") in view of *Aoki*.

Response

This rejection is traversed as follows. To establish a *prima facie* case of obviousness, the Examiner must establish: (1) some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) the prior art references teach or suggest all of the claim limitations. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970).

In the present case, Applicant presents a combination of "exposing the patient to electromagnetic signals ...[and] administering Botulinum toxin". The use of the Botulinum toxin is specifically set forth as:

" ..., wherein the Botulinum toxin synergistically interacts with the electromagnetic signals, by inducing a non-specific immune response to further enhance the bone density stimulation of the exposure of the patient to the electromagnetic signals." (Claim 1; Claim 7 similar.)

The cited art fails to show or suggest this feature. It is further submitted that the Examiner has failed to state a *prima facie* case of obviousness because there is no showing of the reasons why it would be obvious to modify the references to produce the present invention. A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See *Dystar Textilfarben GmbH v. C. H. Patrick*, 464 F.3d 1356 (Fed. Cir. 2006). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed

invention to have been obvious in light of the teachings. *Id.* at 1366.

Regarding the combination, the Botulinum toxin is used in a different treatment, for a different purpose and produces a different result from that described in the cited references. In order to show obviousness under 35 U.S.C. §103, it is necessary to show, "an effect greater than the sum of the several effects taken separately." *Merck v. biocraft Laboratories*, 874 F.2d 804, 10 U.S.P.Q.2 1843, citing *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 U.S.P.Q. 449, 96 S. Ct. 1532, 47 L. Ed. 2d 784 (1976). Referring to the *Sakraida v. Ag Pro* case, the standard for combining elements to produce different results, (citing *Great A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 155 (1950)), is:

"A patent for a combination which only unites old elements with no change in their respective functions... obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men...."

Absent the function (of the Botulinum toxin used by Applicant), there can be no motivation to use the combination. Pursuant to *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007), it is respectfully requested that the Examiner show where a skilled practitioner would have seen a benefit to incorporating Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. This feature is clearly set forth in claims 1 and 7:

"... administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals, such that the Botulinum toxin synergistically interacts with the electromagnetic signals." (claim 1)

Specifically, Applicant requests the association of the claimed feature ("Botulinum toxin synergistically interacts with the electromagnetic signals") with the features of the cited art. It is respectfully submitted that there is no suggestion of such interaction, which would necessarily be prerequisite to an incentive to benefit from the change. Such is not apparent from the cited art.

In order to show obviousness under §103, it is necessary to show an incentive to benefit from the change. *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007).

"The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor. In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well." (*id* at pp. 20-21)

A demonstration of obviousness under §103 requires that the combination represent a design step well within the grasp of a person of ordinary skill in the relevant art. *id.*

"KSR provided convincing evidence that mounting a modular sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. (*id* at pp. 20-21)

Each of the recited combinations (*Ostrow vs. Aoki*, *Becker vs. Aoki*, and *Waltonen vs. Aoki*) fail to suggest the feature of using Botulism toxin as an adjuvant to the exposure to electromagnetic signals for the treatment of osteoporosis. Furthermore, each of the recited combinations fails to suggest using the Botulinum toxin so that:

"... the Botulinum toxin synergistically interacts with the electromagnetic signals." (See claims 1 and 7.)

Accordingly, the cited combination fails to meet the standard for Incentive to Combine under the Rule of *KSR International*. The standard for anticipation under 35 USC 102 and obviousness under 35 USC 103(a) following *KSR International* is detailed in *Forest Labs v. Ivax Pharmaceuticals* (CAFC no. 2007-1059, 2007). In *Forest Labs*, the court determined that a reference mentioned a particular chemical component, but did not explain how to obtain it and

therefore deemed that, "A reference that is not enabling is not anticipating." The court then deemed the product was therefore unobvious over that reference.

Finally, as stated in an earlier Response, given all known osteoporosis treatments at the time of the invention, there is a distinct teaching away from Botulinum toxin as an adjuvant to the exposure to electromagnetic signals for the treatment of osteoporosis (i.e., in combination). See, *KSR International* at page 12, lines 26-27. That is, as osteoporosis art known to Applicant uses electromagnetic signals for the treatment of osteoporosis, or uses neurotoxins (Botulinum toxin) to treat pain. It is respectfully submitted that the cited art fails to show a relationship sufficient to suggest that Botulinum toxin when combined with electromagnetic signals for the treatment of osteoporosis. Thus there would be no motivation to try Botulinum toxin as an adjuvant by people who may likely be considered skilled in the relevant arts. Accordingly, it is submitted that the art of record clearly teaches away from the use of Botulinum toxin as an adjuvant to the exposure to electromagnetic signals. See, *KSR International* at page 12, lines 26-27.

A review of the cited references shows the only motivation is to achieve an end result, which is the treatment of osteoporosis; however there is neither a suggestion of using Botulinum toxin to augment this goal nor a suggestion that a goal of Botulinum toxin treatment be used to achieve this goal. Specifically, there is:

- No showing of "Botulinum toxin synergistically interacting with the electromagnetic signals" (claims 1 and 7) for any purpose relevant to the claimed invention, and
- No showing of a motivation to combine the use of electromagnetic signals with Botulinum toxin.

To use the inventive feature itself to provide motivation is not a showing of motivation to combine; rather it is "hindsight reasoning".

Applying the technology of *KSR International*, the combination is similar to the facetious colloquialism that, in a car, "each gauge adds 10 horsepower." While it is possible to combine

gauges with other modifications to achieve that result (increased power by controlling KSR's throttle), one would still need to show how this is done. Applying this to *KSR International*, one would need to provide the explanation of how the gauge is used to increase horsepower for the same reason the cited references fail to explain how Botulinum toxin treatment aids in bone rejuvenation for the treatment of osteoporosis.

It is respectfully submitted that there is no showing under *KSR International* of a motivation to combine the references because there is no suggestion in any of the references that the combination would have any efficacy at all.

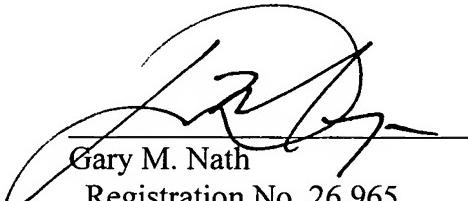
Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-18. Since none of the other prior art of record, whether taken alone or in combination, discloses or suggests all the features of the claimed subject matter, Applicant respectfully submits that independent claims 1 and 7, and all the claims that depend therefrom, are allowable.

CONCLUSION

Applicant respectfully submits that all of the stated grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to call the Applicant's undersigned representative at the number below to expedite prosecution.

Respectfully submitted,
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